UNITED STATES DEPARTMENT OF COMMERCE
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JF

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR		ATTORNEY DOCKET NO.
09/508,923	06/19/00	ROBERTS	N	PM266300

000909
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IM52/1022

EXAMINER	
VANOY, T	
ART UNIT	PAPER NUMBER
1754	6

DATE MAILED: 10/22/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09-508,923	ROBERTS ET AL.
Examiner	**Group Art Unit**
VANOY	1754

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE THREE ——— MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☒ Claim(s) 1-14 is/are pending in the application.

Of the above claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-14 is/are rejected.

☒ Claim(s) 6, 7, 11 AND 13 is/are objected to.

☐ Claim(s) _____ are subject to restriction or election requirement

Application Papers

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☒ ~~The drawing(s)~~ FIG. 1 filed on JUNE 19, 01 is/are objected to by the Examiner

☒ The specification is objected to by the Examiner.

☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119 (a)-(d).

☒ All ☐ Some* ☐ None of the:

☒ Certified copies of the priority documents have been received.

☐ Certified copies of the priority documents have been received in Application No. _____.

☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a))

*Certified copies not received: _____.

Attachment(s)

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☒ Notice of Reference(s) Cited, PTO-892

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Interview Summary, PTO-413

☐ Notice of Informal Patent Application, PTO-152

☐ Other _____

Office Action Summary

DETAILED ACTION

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

a) In the PTO-1449 date stamped, in the references indicated "OR" and "PR" only the "Patent Abstracts of Japan" abstracts for the Japanese references have been considered because only these "Patent Abstracts of Japan" abstracts have been provided. No other documents associated with these Japanese references have been provided so that the other information set forth for the references indicated "OR" and "PR" have been lined through as not being considered.

b) The listing of references on pgs. 1, 2, 44 and 45 in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892 or have been indicated as being considered by the Examiner on form PTO-1449, they have not been considered.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

> The oath or declaration is defective because it does not identify the **city** and state or foreign country for the residence of the inventor "Mr. Norman Bryson Roberts" or the inventor "Mr. Maurice Webb".

Drawings

a) Fig. 1 is objected to because it only illustrates seven sets of plotted data points (i. e. 7 lines) for eight different sets of data (i. e. 8 symbols).

Specification

a) The section title "Brief Description of the Drawings" should be inserted between lines 16 and 17 on pg. 4 in the specification.

b) The PCT abstract for this application is objected to because it does not give any examples of the "mixed metal compound".

c) The use of the **possible** trademark "Aludrox" on pg. 1 ln. 17 has been noted in this application. **If** "Aludrox" is a trademark, **then** it should be capitalized wherever it appears and be accompanied by the generic terminology. **The entire specification should be reviewed to ensure that all trademarks are capitalized and accompanied by their generic terminology.** For example, is "CT100" appearing on pg. 7 ln. 21 (among other places) in the specification a trademark? Is "Altalcite (6)" appearing on pg. 10 ln. 25 in the specification a trademark?

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Objections

a) Claim 6 is objected to under 37 CFR 1.75(c) as being in improper form because multiple dependent claim 6 can not depend on the other multiple dependent claim 3. See MPEP § 608.01(n).

b) In claims 7, 11 and 13, it would be helpful if the "calcium" and "lanthanum" were further limited to "calcium sulfate" and "lanthanum sulfate" (in the manner that the cerium sulfate is limited) to clarify the metes and bounds of these claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicants regard as their invention.

a) In claims 1, 2, 5 and 12, the phrase "phosphate binding capacity of at least 30% by weight of the total weight of the phosphate present" is vague and indefinite in that it is not known where the phosphate is present. The claim language does not particularly point out and distinctly claim where the phosphate is present in, such that at least 30%

by weight of it is removed by the Applicants' composition. Is the "phosphate present" present in a limited amount of blood in the human body? Is the "phosphate present" in the entire volume of blood in the human body? Is the "phosphate present" in only a particular organ of the human body (i. e. the contents within a stomach? a kidney?, both kidneys?, etc. . .).

b) Claims 6-10 call for the use of medicament of the previous claims in a method for preparing a medicament. However, this raises a number of issues:

(i) since claim 1 does not distinguish the "solid mixed meal compound" from the "medicament" and equates the "solid metal compound" with the "medicament", then it would not seem that the product (i. e. the solid metal compound/medicament) would be used in a method for making the product (i. e. the solid metal compound/medicament);

(ii) none of claims 6-10 particularly point out and distinctly set forth *how* the solid metal compound/medicament is used in the method for preparing the medicament, and

(iii) none of claims 6-10 particularly point out and distinctly set forth any steps for the claimed method for making the medicament.

c) Claim 11 does not particularly point out and distinctly set forth what the "solid material" is at the end of the claim, or how it is distinct from the sulfate compounds.

d) In claims 7, 11 and 13, it would be helpful if the "calcium" and "lanthanum" were further limited to "calcium sulfate" and "lanthanum sulfate" (in the manner that the cerium sulfate is limited) to clarify the metes and bounds of these claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The person "having ordinary skill in the art" has the capability of understanding the scientific and engineering principles applicable to the claimed invention. The references of record in this application reasonably reflect this level of skill.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Japan Pat. Doc. No. 5-155,776 A in view of German Pat. Doc. No. 34 02 878 A1 to Dietl.

The English abstract of JP-776 discloses a method for treating hyperphosphatemia by administering a drug/medicament to the patient. The drug/medicament may be in the form of a tablet and contains $Fe(OH)_3$ as the active ingredient. From the information set forth in paragraph no. [0020] in col. 4 in the text of JP-776, it appears that the $Fe(OH)_3$ was made by mixing $FeCl_3$ with 1 molar solution of NaOH and precipitating out of the $Fe(OH)_3$.

Note that Figs. 1 and 2 in JP-776 appear to suggest/disclose that the drug is active at pH values ranging from 2 to 8, in a manner that is not seen to be distinct from the pH limitations in the Applicants' claims.

The difference between the Applicants' claims and JP-776 is that the Applicants' claims call for the use of a mixed metal compound *(whereas JP-776 only uses $Fe(OH)_3$)* which was obtained by forming a precipitate from a solution of a mixture of metal salts *(whereas JP-776 only appears to form a precipitate from a solution of a single metal salt ($FeCl_3$))* wherein the precipitate contains iron(III) and at least one of magnesium, calcium, lanthanum and cerium *(whereas JP-776 only reports the presence of their iron(III) compound)*.

The English abstract of DE-878 reports the use of a drug comprising compounds, such as $CaCO_3$, $Ca(OH)_2$, CaO and/or $CaSO_4$ which act to bind the phosphate, to treat hyperphosphatemia.

It would have been obvious to one of ordinary skill in the art at the time the invention was made *to modify* the process and composition of JP-776 *by including* the $CaSO_4$, etc. . . disclosed in the English abstract of DE-878, *in the manner required by* the Applicants' claims *because* the English abstract of DE-878 discloses that the $CaSO_4$, etc. . . are phosphate binders in drugs used to treat hyperphosphatemia (the same field of endeavor as JP-776 and the Applicants' claims) and the courts have already determined that "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. . . [T]he idea of combining them flows logically from their having been individually taught in the prior art.": please note the discussion of the *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) court decision discussed in section 2144.06 in the MPEP (Aug. 2001).

The following references, which are indicative of the state of the art, are made of record:

U. S. Pat. 6,174,442 B1 disclosing an absorbent for phosphate from an aqueous medium;

U. S. Pat. 6,103,126 disclosing the selective elimination of inorganic phosphate from liquids;

U. S. Pat. 5,968,976 disclosing the use of lanthanum carbonate to treat hyperphosphatemia;

U. S. Pat. 5,846,426 disclosing a process for the selective elimination of phosphate from liquids;

U. S. Pat. 4,994,283 disclosing an iron-calcium mineral supplement;

U. S. Pat. 4,970,079 disclosing a method and composition of oxy-iron compounds for treating hyperphosphatemia, and

U. S. Pat. 4,786,510 disclosing calcium-iron supplements.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy C. Vanoy whose telephone number is 703-308-2540. The examiner can normally be reached on 8 hr. days.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Steven Griffen can be reached on 703-308-1164. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-873-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

Timothy Vanoy
October 19, 2001

Timothy Vanoy
Patent Examiner

Art Unit 1754